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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,137	12/03/2001	Thierry Gandelheid	032880-056	4571 121
7590	07/08/2003			EXAMINER
Allen R. Baum BURNS, DOANE, SWECKER & MATHIS, L.L.P. P.O. Box 1404 Alexandria, VA 22313-1404			THERKORN, ERNEST G	
			ART UNIT	PAPER NUMBER
			1723	

DATE MAILED: 07/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/998,137	GANDELHEID
Examiner THERKORN	Art Unit 1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on MAY 28, 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-5, 9-12, 14-19, 22-25, 29, and 30-41 is/are pending in the application.
- 4a) Of the above, claim(s) 30-34 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-5, 9-12, 14-19, 22-25, 29, and 30-41 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>13</u> | 6) <input type="checkbox"/> Other: _____ |

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Claims 1-5, 9-12, 14-19, and 22-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. "predicting a retention time of the compound of interest from a preparative scale HPLC column" renders the claim indefinite.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 2 1(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-5, 9-12, 14-19, 22-25, and 35-41 are rejected under 35 U.S.C. 102(A) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Collins (WO 01/90739). The claims are considered to read on Collins (WO 01/90739). However, if a difference exists between the claims and Collins (WO 01/90739), it would reside in optimizing the steps of Collins (WO 01/90739). It would have been obvious to optimize the steps of Collins (WO 01/90739) to enhance separation.

Claims 1-5, 9-12, 14-19, 22-25, and 35-41 are rejected under 35 U.S.C. 102(E) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Collins (Pub. No. 2002/0023878). The claims are considered to read on Collins (Pub. No. 2002/0023878). However, if a difference exists between the claims and Collins (Pub. No. 2002/0023878), it would reside in optimizing the steps of Collins (Pub. No. 2002/0023878). It would have been obvious to optimize the steps of Collins (Pub. No. 2002/0023878) to enhance separation.

Claims 2, 3, 9, 10, 11, 14, 23, 24, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Collins (WO 01/90739) or Collins (Pub. No. 2002/0023878) in view of Kibbey (U.S. Patent No. 5,670,054). At best, the claims differ from either Collins (WO 01/90739) or Collins (Pub. No. 2002/0023878) in the clarity of disclosing a UV detector and that a mass spectrometer identifies mass. Each of Collins (WO 01/90739) (pages 24 and 25) and (Collins Pub. No. 2002/0023878) (pages 10 and 11) discloses use of a detector in conjunction with a fraction collector for the preparative chromatography. Kibbey (U.S. Patent No. 5,670,054) (column 7, lines 51-53) discloses a UV detector is used in conjunction with a fraction

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collector for directing flow. Kibbey (U.S. Patent No. 5,670,054) (column 7, lines 44-45) discloses that a mass spectrometer identifies mass. It would have been obvious that either Collins (WO 01/90739) or Collins (Pub. No. 2002/0023878) discloses a UV detector and that his mass spectrometer identifies mass because each of Collins (WO 01/90739) (pages 24 and 25) and (Collins Pub. No. 2002/0023878) (pages 10 and 11) themselves discloses use of a detector in conjunction with a fraction collector for the preparative chromatography and because Kibbey (U.S. Patent No. 5,670,054) (column 7, lines 51-53) discloses a UV detector is used in conjunction with a fraction collector for directing flow and because Kibbey (U.S. Patent No. 5,670,054) (column 7, lines 44-45) discloses that a mass spectrometer identifies mass.

Claims 17-19, 22-25, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Collins (WO 01/90739) or Collins (Pub. No. 2002/0023878) in view of Zambias (U.S. Patent No. 5,766,481). At best, the claims differ from either Collins (WO 01/90739) or Collins (Pub. No. 2002/0023878) in reciting combining streams. Zambias (U.S. Patent No. 5,766,481) (column 1, line 66-column 2, line 40; column 11, line 66-column 12, line 11; and column 12, lines 44-62) discloses that combining streams allows processing a much larger number of compounds with the same equipment. It would have been obvious to combine streams in either Collins (WO 01/90739) or Collins (Pub. No. 2002/0023878) because Zambias (U.S. Patent No. 5,766,481) (column 1, line 66-column 2, line 40; column 11, line 66-column 12, line 11; and column 12, lines 44-62) discloses that combining streams allows processing a much larger number of compounds with the same equipment.

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Claims 23, 24, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Collins (WO 01/90739) or Collins (Pub. No. 2002/0023878) in view of Zambias (U.S. Patent No. 5,766,481) as applied to claims 17-19, 22-25, and 29 above, and further in view of Kibbey (U.S. Patent No. 5,670,054). At best, the claims differ from either Collins (WO 01/90739) or Collins (Pub. No. 2002/0023878) in view of Zambias (U.S. Patent No. 5,766,481) in the clarity of disclosing a UV detector and that a mass spectrometer identifies mass. Each of Collins (WO 01/90739) (pages 24 and 25) and Collins (Pub. No. 2002/0023878) (pages 10 and 11) discloses use of a detector in conjunction with a fraction collector for the preparative chromatography. Kibbey (U.S. Patent No. 5,670,054) (column 7, lines 51-53) discloses a UV detector is used in conjunction with a fraction collector for directing flow. Kibbey (U.S. Patent No. 5,670,054) (column 7, lines 44-45) discloses that a mass spectrometer identifies mass. It would have been obvious that either Collins (WO 01/90739) or Collins (Pub. No. 2002/0023878) in view of Zambias (U.S. Patent No. 5,766,481) discloses a UV detector and that his mass spectrometer identifies mass because each of Collins (WO 01/90739) (pages 24 and 25) and Collins (Pub. No. 2002/0023878) (pages 10 and 11) themselves discloses use of a detector in conjunction with a fraction collector for the preparative chromatography and because Kibbey (U.S. Patent No. 5,670,054) (column 7, lines 51-53) discloses a UV detector is used in conjunction with a fraction collector for directing flow and because Kibbey (U.S. Patent No. 5,670,054) (column 7, lines 44-45) discloses that a mass spectrometer identifies mass.

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The remarks urge the claims are not indefinite. However, the claims state that the retention time of the compound of interest is predicted from a preparative scale HPLC column. However, a fair reading of the specification would suggest that the retention time of the compound of interest is predicted from the analytical HPLC column. As such, the claims are considered to be indefinite because they appear to be contrary to the instant specification.

The remarks urge patentability based upon use of a static correlation function. However, Collins (Pub. No. 2002/0023878) discloses static correlation function, i.e., constant conditions on page 5, paragraph 75, lines 10-15 and Collins (WO 01/90739) discloses static correlation function, i.e., constant conditions on page 12, lines 3-7. In addition, page 10, lines 24-28 of the instant specification indicates that static and dynamic correlation functions are interchangeable.

The remarks urge patentability based upon predicting a retention time. However, Collins (Pub. No. 2002/0023878) discloses predicting a retention time on page 5, paragraph 78, lines 1-5 and Collins (WO 01/90739) discloses predicting a retention time on page 13, lines 1-5.

The remarks urge patentability based upon selecting a window of time. However, Collins (Pub. No. 2002/0023878) discloses selecting a window of time on page 7, paragraph 91, lines 3-6 and Collins (WO 01/90739) discloses selecting a window of time on page 15, lines 23-25.

Applicant's submission of an information disclosure statement under 37 CFR 1.97© with the fee set forth in 37 CFR 1.17(p) on May 28, 2003 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP §

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609(B)(2)(I). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to E. Therkorn at telephone number (703) 308-0362.



**Ernest G. Therkorn
Primary Examiner
Art Unit 1723**

EGT/12
July 2, 2003